REMARKS

Applicants have received and carefully reviewed the Office Action mailed March 7, 2011. Currently, claims 1, 4, 5, 8, 28-30, 32, and 33 have been rejected. With this Amendment, claims 1, 28, 38, and 40 have been amended. No new matter has been added. As such, claims 1, 4-5, 8, 28-30, and 32-40 remain pending. Favorable consideration of the following remarks is respectfully requested.

Claim Rejections – 35 U.S.C. § 112

In paragraph 3 of the Office Action, claims 1, 4, 5, 8, 28-30, and 32-40 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Office Action asserts that the specification contains no disclosure of what constitutes the intermediate region or its length, thus there is no way for one of skill in the art to know what delineates the intermediate region or how to measure it. Applicants respectfully disagree. However in the interest of advancing prosecution, claim 1 has been amended to recite, "an intermediate region disposed between the proximal end region and the distal end region" and "wherein the intermediate region of the branch guidewire enclosure is at least 10 cm to 100 cm in length between the bond and the balloon." This claim language is fully supported by the original disclosure at, for example, paragraph 33 of the published application. Applicants submit that one of ordinary skill in the art could easily measure the claimed intermediate region.

In paragraph 4 of the Office Action, claims 28, 38, and 40 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claims were rejected for reciting a dimension of "around 10 cm or more" without an upper limit, while the specification only provides support for a distance of 1-100 cm. The claims have been amended to include the upper limit of 100 cm.

In paragraph 6 of the Office Action, claim 28 was rejected under 35 U.S.C. § 112, second paragraph, for lack of antecedent basis. Applicants respectfully disagree. Line 12 of claim 28 recites, "a bond material configured to form a bond", which provides the necessary antecedent basis for the later recitations of "the bond."

In paragraph 7 of the Office Action, claim 5 was rejected under 35 U.S.C. § 112, second paragraph. The Office Action states that claim 1 recites the intermediate portion (not including the distance of the proximal end portion or the distal end portion) is at least 10 cm. The Office

Action then states that it is not clear how the distance from the port to the distal end of the catheter (including at least the distance of the branch guidewire enclosure) is 10 cm when only the intermediate portion of the guidewire enclosure is 10 cm. Applicants note that claim 1, as amended, recites the intermediate portion is at least 10 cm to 100 cm.

The claims as amended are believed to satisfy the requirements of 35 U.S.C. § 112. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim Rejections – 35 U.S.C. § 103

In paragraph 9 of the Final Office Action, claims 1, 4, and 39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Keith et al. (U.S. Patent No. 6,273,879) in view of Adams et al. (U.S. Patent No. 6,099,497) and further in view of Sirhan (U.S. Patent No. 5,743,875). After careful review, Applicants respectfully traverse this rejection. Applicants note that claims 28, 38, and 40 were not included in the statement of the rejection but are mentioned in paragraph 15 on page 7. Applicants will address claims 28, 38, and 40 as if they were included in the rejection. Applicants respectfully request clarification of which claims are included in the rejection in the next Office Action.

Claim 1, as amended, recites:

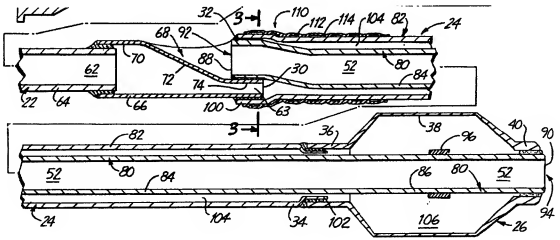
> 1. A catheter system for positioning a stent at a vessel bifurcation, the catheter system comprising:
> a catheter including a proximal end and a distal end, the catheter comprising:
> a first tubular member including a proximal end and a distal end, the first tubular member defining an inflation lumen of the catheter and extending distally from the proximal end of the catheter;
> a second tubular member defining a main guidewire lumen, wherein the distal end of the second tubular member is a distal end of the catheter and the proximal end of the second tubular member defines a main guidewire exit port, wherein the main guidewire lumen is configured to receive a main vessel guidewire therethrough, wherein the second tubular member is at least partially disposed within the inflation lumen of the first tubular member;
> a balloon including a proximal waist coupled to the first tubular member adjacent to the distal end of the first tubular member and a distal waist coupled to the second tubular member adjacent to the distal end of the second tubular member;
> a branch guidewire enclosure positioned alongside the first tubular member, wherein the branch guidewire enclosure defines a lumen configured to receive a branch vessel guidewire therethrough, the branch guidewire enclosure including a proximal end region having a proximal end, a distal end region, and an

intermediate region disposed between the proximal end region and the distal end region, the proximal end of the branch guidewire enclosure defining a branch guidewire exit port; and

a stent having a lumen and a side opening in a wall thereof, the stent positioned about at least a portion of the balloon, and wherein a distal portion of the branch guidewire enclosure is positioned through the lumen of the stent and exits at the side opening;

wherein the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at a bond at the proximal end region of the branch guidewire enclosure, wherein the intermediate region of the branch guidewire enclosure is at least 10 cm to 100 cm in length between the bond and the balloon, wherein the main guidewire exit port and the branch guidewire exit port are located proximal of the stent and distal of the proximal end of the catheter.

Nothing in the cited portions of Keith et al., Adams et al., or Sirhan et al. appears to disclose such features. In paragraph 10, the Office Action asserts that Keith disclose a device including a balloon 26 including a proximal waist 36 coupled to the first tubular member (asserted as 22/24) adjacent to the distal end of the first tubular member. Applicants respectfully disagree. Keith teaches, "the main shaft section 22 thus has a longitudinally extending inflation lumen 62 extending therethrough from its proximal end 28 to its distal end 30." As can be seen in FIG. 2 reproduced below, the distal end 30 of main shaft section 22 ends proximal to balloon 26. Instead of the proximal waist 36 of the balloon being coupled to the first tubular member 22, as asserted in the Office Action, Keith appears to teach proximal waist 36 coupled to the outer sleeve 82 of the intermediate sleeve 24. Neither Adams et al. nor Sirhan et al. appear to teach what Keith lacks.



The Office Action acknowledges that Keith does not disclose a branch guidewire enclosure or a stent, and asserts that it would have been obvious to incorporate the two guidewire system and stent of Adams so the system of Keith would be capable of delivering a stent to an ostium or bifurcation. Regarding the claim limitation of "wherein the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at a bond at the proximal end region of the branch guidewire enclosure," the Office Action asserts that it would have been obvious to bond the secondary guidewire structure to the first tubular member of Keith since the first tubular member is the outermost surface of the catheter. The Office Action further asserts that Adams shows in FIG. 17 and 18 that the guidewire enclosure is bonded to the tubular member at a distance from the proximal end of the balloon. The Office Action has not asserted that Adams teaches bonding the branch guidewire enclosure to the tubular member only at a bond at the proximal end region of the branch guidewire enclosure. The Office Action has not specifically addressed this claim element. None of Keith, Adams, or Sirhan appear to teach or suggest such a structure. While Adams appears to teach a second guidewire lumen 136 disposed adjacent the first guidewire lumen 134, the reference does not appear to teach any specific type or location of bonding between the two lumens. Adams thus cannot be seen to provide any teaching or motivation for modifying Keith to have a branch guidewire enclosure bonded only to the first tubular member and only bonded at a bond at the proximal end region of the branch guidewire enclosure, as recited in the claim. Further, in the absence of any teaching or suggestion in the references, the Office Action has not provided any rational reason as to why one of ordinary skill in the art would have been motivated to modify Keith to include such a bonding structure.

The Office Action asserts that because Sirhan discloses a balloon catheter having a guidewire exit port located at between 5 cm and 45 cm from the distal end of the catheter, it would have been obvious to modify the distance of the guidewire port and thus the intermediate portion of the branch guidewire portion in order to suit the particular intended use. Applicants respectfully disagree. First, Applicants submit that "in order to suit the particular intended use" does not provide the necessary rational reason required for obviousness. It appears the Office Action is asserting that one could modify the location of a guidewire port if one wanted to.

The Supreme Court in *KSR Int'l Co. v. Teleflex Inc.* quotes *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) stated:

> "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness".

Emphasis added; see page 14 of the April 30, 2007 Decision. The Office Action has not provided any articulated reasoning with rational underpinning to support the conclusion of obviousness. The Office Action appears to be asserting that one could modify Keith, Adams, and Sirhan to achieve the claimed structure, which is clearly an improper ground for obviousness. The Court in KSR further stated:

> a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.

See page 14 of the April 30, 2007 Decision. The Office Action has not provided any objective reason to modify Keith, Adams, and Sirhan in the manner recited in claim 1, other than relying on the instant specification, which is clear error.

Second, Applicants submit that even though Sirhan teaches a single, main guidewire exit port located 5-45 cm from the distal end of the catheter, this does not provide any motivation for modifying Keith and Adams to achieve an "intermediate region of the branch guidewire enclosure is at least 10 cm to 100 cm in length between the bond and the balloon" as recited in the claim. Further, there is nothing in Keith, Adams, and Sirhan that teaches or suggests the combination of "wherein the branch guidewire enclosure is bonded only to the first tubular member and only bonded to the first tubular member at a bond at the proximal end region of the branch guidewire enclosure" and "wherein the intermediate region of the branch guidewire enclosure is at least 10 cm to 100 cm in length between the bond and the balloon." The Office Action has not provided any teaching or suggestion of the claimed structure. Further there is no rational reason for one of ordinary skill in the art to modify the references to achieve the claimed structure. The Office Action asserts the motivation for modifying Keith to achieve the claimed structure is to modify a dimension to suit the intended use of the device for example size of the patient or location of the body being treated. Applicants submit this "motivation" appears to be based on the present specification, which is improper. Alternatively, the motivation appears to be one of modify Keith merely because on "could," which is improper. See *KSR* quote above.

For at least these reasons, claim 1 is believed to be patentable over Keith et al. in view of Adams et al. and Sirhan et al. For similar reasons and others, claims 4 and 39 which depend

from claim 1 and include additional distinguishing features, are believed to be patentable over Keith et al. in view of Adams et al.

Claims 28, 38, and 40 were not included in the statement of the rejection, but the Office Action addresses the claims briefly in paragraph 15. The Office Action asserts that Adams and Sirhan teach modifying dimensions, thus it would be well within the level of one of ordinary skill in the art to modify the distance of the bond to meet the limitations of the claim. Applicants respectfully disagree. As discussed above, Adams does not appear to provide any teaching regarding how and where the first and second guidewire lumens are bonded. Further, Adams does not appear to teach or suggest any dimensions for the secondary guidewire lumen between any possible bonding region and the balloon. Also as discussed above, while Sirhan appears to provide dimensions for the location of a primary guidewire port, this does not provide any suggestion or motivation for one of ordinary skill in the art to modify the length of a branch guidewire enclosure distal of a single bond region.

Additionally the asserted motivation of modifying dimensions "to suit the intended use of the device" does not provide the rational reason required for obviousness. The Office Action appears to be asserting that it would have been obvious to modify Keith, if one wanted to do so. Applicants submit this is not a proper basis for obviousness. For at least these reasons, claims 28, 38, and 40 are believed to be patentable over Keith et al. in view of Adams et al. and Sirhan et al.

Claims free of the art

Applicants note that only claims 1, 4, and 39 were included in the statement of the rejection in paragraph 9, and no other art rejection was made. It appears that claims 5, 8, 28-30, and 32-40 are free of the prior art. If this is incorrect, Applicants respectfully request clarification of the rejections in a non-final rejection, so that Applicants may have an opportunity to properly respond to any such rejections.

Conclusion

Reconsideration and further examination of the rejections are respectfully requested. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

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By their Attorney,

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/j. scot wickhem/

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